IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

ROSE MARSH,	§	
	§	
***Plaintiff*,**	§	
	§	
v.	§	**Case No. _____**
	§	**JURY TRIAL DEMANDED**
ROYAL PHILIPS; PHILIPS NORTH AMERICA, LLC; PHILIPS HOLDING USA, INC.; PHILIPS RESPIRONICS; and PHILIPS RS NORTH AMERICA, LLC;	§	
	§	
***Defendants*.**	§	

COMPLAINT

Plaintiff Rose Marsh, by and through her undersigned counsel, hereby submits the following First Amended Complaint and Demand for Jury Trial against Defendants Royal Philips, Philips North America LLC ("Philips NA"), Philips Holding USA, Inc. ("PHUSA"), Philips Respironics, and Philips RS North America LLC ("Philips RS") (collectively referred to as "Philips" or the "Defendants") and alleges the following upon personal knowledge and belief and investigation of counsel:

I. INTRODUCTION

1. Philips manufactures, markets, sells, and distributes a variety of products for sleep and home respiratory care.

2. Philips manufactures, markets, imports, sells, and distributes a variety of Continuous Positive Airway Pressure (CPAP) and BiLevel Positive Airway Pressure (BiPAP) devices for patients with obstructive sleep apnea ("OSA").

3. Philips also manufactures, markets, imports, sells, and distributes a variety of

ventilator devices for patients with respiratory conditions.

4. On or about June 14, 2021, Philips issued a recall notification for many of its CPAP and BiLevel PAP devices as well as a number of its ventilator devices.

5. In its recall notification, Philips advised of potential health risks related to the sound abatement foam used in the affected devices.

6. Philips informed patients using these affected devices of potential risks from exposure to degraded sound abatement foam particles and exposure to chemical emissions from the sound abatement foam material.

7. Specifically, Philips notified patients that the risks related to issues with the sound abatement foam include headache, irritation, inflammation, respiratory issues, and possible toxic and carcinogenic effects.

8. Plaintiff Rose Marsh was prescribed and purchased one of Philips' Recalled Products, a Philips Dream Wear, to treat her sleep apnea.

9. Plaintiff used the Philips Dream Wear device (the "subject device"), one of Philips' Recalled Products, on a daily basis for a number of years.

10. In 2019, Plaintiff was diagnosed with lung cancer and related lung disease. Plaintiff has also suffered pneumonia and acidosis since using the device. Plaintiff's conditions, including chronic lung disease, have worsened since he began using the Dream Wear device in 2015.

11. As a direct and proximate result of Philips' conduct, Plaintiff has suffered serious and substantial life-altering injuries.

12. As a direct and proximate result of the subject device, manufactured, marketed, imported, sold, and distributed by Philips, Plaintiff has suffered physical, emotional, and financial injuries, including lung cancer and related lung disease.

II. PARTIES, JURISDICTION, AND VENUE

13. Plaintiff Rose Marsh ("Plaintiff") is an adult resident and citizen of the State of North Carolina, residing in Cumberland County, North Carolina.

14. Plaintiff was prescribed the use of the subject device while a resident of Cumberland County, North Carolina she purchased the subject device in North Carolina, and the majority of her use of the use of the subject device occurred in North Carolina.

15. Defendant Philips North America LLC ("Philips NA") is a Limited Liability Company incorporated in Delaware, with its principal place of business located at 3000 Minuteman Road, Andover, MA 01810. Philips NA is a wholly owned subsidiary of Royal Philips. Philips NA manages the operation of Royal Philips' various lines of business, including Philips RS, in North America. The sole member of Philips NA is Defendant Philips Holding USA, Inc. ("PHUSA"), which is a Delaware corporation with its principal place of business located at 222 Jacobs Street, Floor 3, Cambridge, Massachusetts 02141. Philips NA is 100% owned by PHUSA. Philips NA may be served through its registered agent the Corporation Service Company at 2626 Glenwood Ave., Suite 550, Raleigh, North Carolina 27608.

16. Defendant Philips Holding USA, Inc. ("PHUSA") is a Delaware corporation with its principal place of business located at 222 Jacobs Street, 3rd Floor, Cambridge, Massachusetts 02141. PHUSA is a holding company that is the sole member of Defendant Philips NA. PHUSA may be served through its registered agent, the Corporation Service Company at at 2626 Glenwood Ave., Suite 550, Raleigh, North Carolina 27608.

17. Defendant Philips RS North America LLC ("Philips RS") is a Delaware Limited Liability Company with its principal place of business located in Pittsburgh, Pennsylvania. Philips RS was formerly operated under the business name Respironics, Inc. ("Respironics").

Royal Philips acquired Respironics in 2008. Philips RS is wholly owned by a single member, Philips RS North America Holding Corporation, a Delaware corporation with its principal place of business in Cambridge, Massachusetts.

18. Philips NA, PHUSA, and Philips RS are hereinafter collectively referred to as "Philips" or the "Defendants."

19. Upon information and belief, Defendants have purposefully availed themselves of the benefits of doing business in North Carolina through manufacturing, designing, labeling, marketing, distributing, supplying and/or selling, and other products for the treatment of obstructive sleep apnea, including the Dream Wear device prescribed for and purchased by Plaintiff at issue in this lawsuit (the "subject device"), and by placing such products into the stream of commerce for those purposes.

20. At all times pertinent to this Complaint, Defendants were the mere alter egos or instrumentalities of each other. There is such a unity of interest and ownership between Defendants that the separate personalities of their entities ceased to exist. Defendants operated as a single enterprise, equally controlled each other's business affairs, commingled their assets and funds, disregarded corporate formalities, and used each other as a corporate shield to defeat justice, perpetuate fraud and evade contractual and/or tort liability.

21. At all times pertinent to this Complaint, Defendants acted in all respects as agents or apparent agents of one another.

22. At all times pertinent to this Complaint, Defendants acted in concert in the designing, manufacturing, marketing, promoting, advertising, and selling of devices for the treatment of obstructive sleep apnea, including the subject device. Defendants combined their property and labor in a joint undertaking for profit, with rights of mutual control over each other,

rendering them jointly liable to Plaintiff.

23. Defendants regularly transact business in North Carolina, including the marketing and selling devices for the treatment of obstructive sleep apnea, derive substantial revenue from their business transactions in North Carolina, and have purposely availed themselves of the privilege of doing business in North Carolina.

24. Defendants shipped or participated in shipping the subject device and other devices with the reasonable expectation that the devices could or would find their way to North Carolina through the stream of commerce.

25. Defendants' actions in marketing and selling their devices in North Carolina should have led them to reasonably anticipate being subject to the jurisdiction of a North Carolina court.

26. Defendants have sufficient "minimum contacts" with North Carolina that subjecting them to personal jurisdiction in the state does not offend traditional notions of fair play and substantial justice.

27. As detailed below, Plaintiff suffered injuries in Cumberland County, North Carolina from the subject device that Defendants negligently designed and/or manufactured either in North Carolina or outside of North Carolina. Thus, Defendants committed a tort either in North Carolina or outside of the state that caused injuries in North Carolina.

28. This Court has subject-matter jurisdiction over this action pursuant to 28 U.S.C. § 1332(a) based on complete diversity of citizenship between Plaintiff and all Defendants. The amount in controversy exceeds $75,000, exclusive of interest and costs.

29. This Court has personal jurisdiction over Defendants, who at all relevant times were engaged in the manufacturing, designing, labeling, marketing, distributing, supplying and/or

selling of their products, and introduced such products for the treatment of obstructive sleep apnea into interstate commerce with knowledge and intent that such products be sold in the State of North Carolina. Each Defendant has sufficient minimum contacts with the state of North Carolina to be sued and be required to defend here.

30. Venue is proper in this District under 28 U.S.C. § 1391 because a substantial part of the events or omissions giving rise to the claim occurred in this District. Furthermore, each Defendant purposefully availed itself of the benefits of doing business in North Carolina through manufacturing, designing, labeling, marketing, distributing, supplying and/or selling of devices for the treatment of obstructive sleep apnea.

31. This Court's exercise of personal jurisdiction over Defendants comports with due process.

III. BACKGROUND

32. At all relevant times, Defendants manufactured, marketed, sold, and distributed a lineup of CPAP and BiPAP devices as well as ventilator devices under its "Sleep & Respiratory Care" portfolio. These devices are designed to assist individuals with a number of sleep, breathing, and other respiratory conditions, including sleep apnea.

33. Defendants sought and obtained Food and Drug Administration ("FDA") approval to market the Recalled Products, including the subject device used by Plaintiff, under Section 510(k) of the Medical Device Amendment to the Food, Drug and Cosmetics Act. Section 510(k) allows marketing of medical devices if the device is deemed substantially equivalent to other legally marketed predicate devices marketed prior to May 28, 1976. No formal review for safety or efficacy is required.

A. Continuous Positive Airway Pressure Therapy

34. Continuous Positive Airway Pressure ("CPAP") therapy is a common nonsurgical treatment primarily used to treat sleep apnea. CPAP therapy typically involves the use of a nasal or facemask device and a CPAP device helps individuals breathe by increasing the air pressure in an individual's throat.

35. Sleep apnea is a common sleep disorder characterized by repeated interruptions in breathing throughout an individual's sleep cycle. These interruptions, called "apneas," are caused when the soft tissue in an individual's airway collapses. The airway collapse prevents oxygen from reaching the individual's lungs which can cause a buildup of carbon dioxide. If the individual's brain senses the buildup of carbon dioxide, it will briefly rouse the individual from sleep so that the individual's airway can reopen. Often these interruptions are so brief that the individual will not remember. Despite the brevity of the interruptions, the sleep cycle disruption caused by sleep apnea can dramatically impact a person's lifestyle, including negatively impacting energy, mental performance, and long-term health. CPAP therapy helps treat sleep apnea by preventing the person's airway from collapsing while breathing during sleep cycles, which can help prevent interruptions in breathing.

B. Bi-Level Positive Airway Pressure Therapy ("BiPAP")

36. BiPAP therapy is a common alternative to CPAP therapy for treating sleep apnea. Similar to CPAP therapy, BiPAP therapy is nonsurgical and involves the use of a nasal or facemask device to maintain air pressure in an individual's airway. BiPAP is distinguishable from CPAP therapy, however, because BiPAP devices deliver two alternating levels—inspiratory and expiratory—of pressurized air into a person's airway, rather than the single continuous level of pressurized air delivered by a CPAP device. The inspiratory positive

airway pressure assists a person as a breath is taken in. Conversely, the expiratory positive airway pressure is applied to allow a person to comfortably breathe out. BiPAP devices deliver one level of pressurize air (the inspiratory positive level) to assist as a person inhales, and another level (the expiratory level) as a person exhales.

C. Philips' Sleep & Respiratory Care Devices Were Endangering its Users

37. On April 26, 2021, as part of its Quarterly Report for Q1 2021, Philips disclosed for the first time, under a section entitled "Regulatory Update," that device user reports had led to a discovery that the type of polyester-based polyurethane ("PE-PUR Foam") "sound abatement" foam Philips used to minimize noise in several CPAP and BiPAP respirators posed health risks to its users. Specifically, Philips disclosed that "the [PE-PUR] foam may degrade under certain circumstances, influenced by factors including use of unapproved cleaning methods, such as ozone[], and certain environmental conditions involving high humidity and temperature."[1]

38. On June 14, 2021, as a result of extensive ongoing review following the announcement on April 26, 2021, Philips issued a recall notification for specific affected devices.[2]

39. In its recall notification, Philips identified examples of potential risks which include exposure to degraded sound abatement foam particles and exposure to chemical emissions from the sound abatement foam material.[3]

40. Philips reported that, based on lab testing and evaluations, it may be possible that these potential health risks could result in a wide range of potential patient impacts, including

[1] *First Quarter Results*, PHILIPS (Apr. 26 2021), https://www.results.philips.com/publications/q121/downloads/pdf/en/philips-first-quarter-results-2021-report.pdf (accessed August 22, 2021).
[2] *Medical Device Recall Notification*, PHILIPS RESPIRONICS (June 14, 2021), https://www.usa.philips.com/healthcare/e/sleep/communications/src-update#section_2 (accessed August 22, 2021).
[3] *Id.*

transient potential injuries, symptoms, and complications, as well as possibly serious injury which can be life-threatening or cause permanent impairment, or require medical intervention to preclude permanent impairment.[4]

41. According to Philips' recall notice, Philips "received several complaints regarding the presence of black debris/particles within the airpath circuit (extending from the device outlet, humidifier, tubing, and mask)."[5]

42. According to Philips' recall notice, the PE-PUR Foam used in Recalled Products puts Recalled Device users at risk of suffering from the following health harms: "The potential risks of particulate exposure include: Irritation (skin, eye, and respiratory tract), inflammatory response, headache, asthma, adverse effects to other organs (e.g. kidneys and liver) and toxic carcinogenic affects. The potential risks of chemical exposure due to off-gassing include: headache/dizziness, irritation (eyes, nose, respiratory tract, skin), hypersensitivity, nausea/vomiting, toxic and carcinogenic effects."[6]

43. On June 14, 2021, Philips also issued a brief report titled "Clinical Information for Physicians." In this report, Philips disclosed that "[l]ab analysis of the degraded foam reveals the presence of potentially harmful chemicals including:

-Toluene Diamine

-Toluene Diisocyanate

-Diethylene glycol."[7]

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[4] *Id.*
[5] Philips Recall Letter, *available at* https://www.philips.com/c-dam/b2bhc/master/landing-pages/src/update/documents/philips-recall-letter-2021-05-a-2021-06-a.pdf (accessed August 22, 2021).
[6] *Id.*
[7] *Sleep and Respiratory Care update*, https://www.philips.com/c-dam/b2bhc/master/landing-pages/src/update/documents/philips-recall-clinical-information-for-physicians-and-providers.pdf (accessed August 22, 2021).

44. In the same report, Philips also disclosed that lab testing performed by and for Philips had also identified the presence of Volatile Organic Compounds (VOCS) which may be emitted from the sound abatement foam component of the affected devices. "VOCs are emitted as gases from the foam included in the [affected devices] and may have short- and long-term adverse health effects." Standard testing identified two compounds of concern may be emitted from the foam that are outside of safety thresholds. The compounds identified are the following:

-Dimethyl Diazine

-Phenol, 2,6-bis (1,1-dimethylethyl)-4-(1-methylpropyl)[8]

D. Philips' Recalled Products

45. In total, Philips announced that "[b]etween 3 million and 4 million" devices are targeted in the recall.[9]

46. The list of the devices recalled by Phillips (the "Recalled Products") include:[10]

CPAP AND BIPAP DEVICES	
Device Type	**Model Name and Number (All Serial Numbers)**
Continuous Ventilator, Minimum Ventilatory Support, Facility Use	E30 (Emergency Use Authorization)
Continuous Ventilator, Non-life Supporting	DreamStation ASV
	DreamStation ST, AVAPS
	SystemOne ASV4
	C-Series ASV
	C-Series S/T and AVAPS
	OmniLab Advanced+

[8] *Id.*
[9] Sterling, Toby, *Philips recalls ventilators, sleep apnea machines due to health risks*, Reuters.com, June 14, 2021, *available at*, https://www.reuters.com/business/healthcare-pharmaceuticals/philips-recalls-some-3-4-million-cpap-ventilator-machines-due-foam-part-2021-06-14/ (accessed August 22, 2021).
[10] *Certain Philips Respironics Ventilators, BiPAP, and CPAP Machines Recalled Due to Potential Health Risks: FDA Safety Communication*, https://www.fda.gov/medical-devices/safety-communications/certain-philips-respironics-ventilators-bipap-and-cpap-machines-recalled-due-potential-health-risks (accessed August 22, 2021).

Noncontinuous Ventilator	SystemOne (Q-Series)
	DreamStation
	DreamStation Go
	Dorma 400
	Dorma 500
	REMstar SE Auto
VENTILATORS	
Device Type	**Model Name and Number (All Serial Numbers)**
Continuous Ventilator	Trilogy 100
	Trilogy 200
	Garbin Plus, Aeris, LifeVent
Continuous Ventilator, Minimum Ventilatory Support, Facility Use	A-Series BiPAP Hybrid A30 (not marketed in US)
	A-Series BiPAP V30 Auto
Continuous Ventilator, Non-life Supporting	A-Series BiPAP A40
	A-Series BiPAP A30

47. Philips issued the following advice to patients using any of the Recalled Products:

- "**For patients using BiLevel PAP and CPAP devices**: Discontinue use of affected units and consult with physicians to determine the benefits of continuing therapy and potential risks."[11]
- **"For patients using life-sustaining mechanical ventilator devices: DO NOT discontinue or alter prescribed therapy, without consulting physicians to determine appropriate next steps**."[12]

E. Philips Unreasonably Delayed its Recall

48. The United States Food and Drug Administration ("FDA") has identified the recall "as a Class I recall, the most serious type of recall" and has advised that the "[u]se of these devices may cause serious injuries or death."[13]

[11] *Medical Device Recall Notification*, PHILIPS RESPIRONICS (June 14, 2021), https://www.usa.philips.com/healthcare/e/sleep/communications/src-update#section_2 (accessed August 22, 2021).
[12] *Id.*
[13] *Philips Respironics Recalls Certain Continuous and Non-Continuous Ventilators, including CPAP and BiPAP, Due to Risk of Exposure to Debris and Chemicals*, U.S. Food & Drug Administration, https://www.fda.gov/medical-devices/medical-device-recalls/philips-respironics-recalls-certain-continuous-and-non-continuous-ventilators-including-cpap-and (accessed August 23, 2021).

49. Upon information and belief, Defendants knew of the potential risks long before their recall was issued.

50. Thus, because of user reports and other testing performed by and on behalf of Defendants, Defendants were aware of the degradation of the PE-PUR sound abatement foam used in the Recalled Products, yet continued to manufacture, market, and sell the Recalled Products with such awareness for a significant period of time. During this period, Defendants unreasonably and unjustly profited from the manufacture and sale of the Recalled Products and unreasonably put users of the Recalled Products at risk of developing adverse health effects.

F. Plaintiff Rose Marsh

51. In or around January 2015, Plaintiff was prescribed the use of and purchased a Dream Wear device (the "subject device"). The subject device prescribed for and purchased by Plaintiff was one of the Recalled Products.

52. At the time Plaintiff was prescribed the use of and purchased the subject device, he was a resident and citizen of Cumberland County, North Carolina.

53. Since 2015, Plaintiff used the subject device daily to treat her sleep apnea.

54. At all times Plaintiff used the subject device, he used the subject device in accordance with the guidelines, manual, and instructions for use set forth by Defendants.

55. At all times Plaintiff used the subject device, he used the subject device for a purpose for which the subject device was marketed, designed, and intended.

56. At all times Plaintiff used the subject device, he used the subject device in accordance with the directions and instructions issued by her physician who prescribed the use of the subject device.

57. As a result of using the subject device, Plaintiff suffered personal injuries and

damages as alleged herein. These injuries would not have occurred but for the defective nature of the subject device and/or Defendants' wrongful conduct.

58. Plaintiff was diagnosed with lung cancer on or around January 1, 2019.

59. By reason of the foregoing, Plaintiff has had to undergo significant treatment, will be required to undergo significant treatment in the future, and now requires constant and continuous medical monitoring and treatment due to the defective nature of the subject device and/or Defendants' wrongful conduct.

60. As a result of the aforesaid conduct and subject device manufactured, designed, sold, distributed, advertised, and promoted by Defendants, Plaintiff was injured, resulting in severe mental and physical pain and suffering. Such injuries have caused permanent disability to her person. As a result of such injuries, Plaintiff has suffered damages for which compensatory damages should be awarded.

IV. CAUSES OF ACTION

COUNT I
PRODUCTS LIABILITY: DEFECTIVE DESIGN

61. Plaintiff hereby incorporates by reference each of the allegations set forth in this Complaint as if fully set forth herein.

62. Defendants are manufacturers, as defined by North Carolina General Statutes Ch. 99B-1, who designed, developed, manufactured, tested, inspected, packaged, promoted, marketed, distributed, labeled, and sold the Recalled Products.

63. Defendants placed their Recalled Products, into the stream of commerce.

64. Defendants expected their Recalled Products to reach, and they did reach consumers, including Plaintiff, without substantial alteration in the condition in which it was sold.

65. The Recalled Products are defective in their design or formulation. They are not reasonably fit, suitable or safe for their intended purpose and/or their foreseeable risks exceed the benefits associated with their design. They lack efficacy, poses a greater likelihood of injury and is more dangerous than other available devices indicated for the same conditions and uses. If the design defects were known at the time of manufacture, a reasonable person would have concluded that the utility of the Recalled Products did not outweigh their risks.

66. The defective condition of the Recalled Products rendered them unreasonably dangerous and/or not reasonably safe in one or more of the following ways:

67. The Recalled Products were more dangerous than would be reasonably contemplated by the ordinary patient or doctor. Plaintiff was unaware of the significant hazards and defects in the Recalled Products including the subject device.

68. The subject device was in this defective condition at the time it left the hands of Defendants. The subject device was expected to and did reach Plaintiff and Plaintiff's doctor without substantial change in the condition in which it was designed, manufactured, labeled, sold, distributed, marketed, promoted, supplied, and otherwise released into the stream of commerce.

69. At the time Plaintiff used the subject device, it was represented to be safe and free from latent defects.

70. During the period that Plaintiff used the subject device, it was being utilized in a manner that was intended by Defendants.

71. The subject device was more dangerous than would be reasonably contemplated by the ordinary patient or doctor.

72. Defendants knew or should have known of the danger associated with the use of their Recalled Products, including the subject device, but continued to design, manufacture, sell,

distribute, market, promote and/or supply the Recalled Products so as to maximize sales and profits at the expense of the public health and safety, in conscious disregard of the foreseeable harm caused by the Recalled Products.

73. The subject device is defective in its design or formulation in that it is not reasonably fit, suitable, or safe for its intended purpose and/or its foreseeable risks exceed the benefits associated with its design.

74. The subject device is defective in design because it causes injuries including but not limited to headaches, irritation of the skin, eye, and respiratory tract, inflammation respiratory issues, asthma, adverse effect to organs (including the kidneys and liver), hypersensitivity, nausea, vomiting, and toxic and carcinogenic effects. It is more dangerous than other available devices indicated for similar conditions and uses, and the utility of the device does not outweigh its risks.

75. The defective condition of the subject device rendered it unreasonably dangerous and/or not reasonably safe, and the device was in this defective condition at the time it left the hands of Defendants. Subject device was expected to and did reach Plaintiff and her physician without substantial change in the condition in which it was designed, manufactured, labeled, sold, distributed, marketed, promoted, supplied, and otherwise released into the stream of commerce.

76. The subject device was used for its intended purposes by Plaintiff and the subject device was not materially altered or modified prior to its use.

77. The subject device is defective in design because the PE-PUR foam comprising part of the device can degrade into particles that enter the device's air pathway and can off-gas certain chemicals.

78. At or before the time the subject device was released on the market and/or sold to

Plaintiff, Defendants could have designed the product to make it less prone to causing the above listed health harms, a technically feasible safer alternative design that would have prevented the harm Plaintiff suffered without substantially impairing the function of the device.

79. Plaintiff was not able to discover, nor could he have discovered through the exercise of reasonable diligence, the defective nature of the subject device. Further, in no way could Plaintiff have known that Defendants had designed, developed, and manufactured the subject device in a way as to make the risk of harm or injury outweigh any benefits.

80. Defendants knew or should have known that the Recalled Products, including the subject device, would be prescribed to patients and that physicians and patients were relying on them to furnish a suitable device. Further, Defendants knew or should have known that patients for whom the Recalled Products would be used, such as Plaintiff, could be and would be affected by the defective design and composition of the devices.

81. Defendants researched, designed, manufactured, tested, advertised, promoted, marketed, sold, and distributed a defective device which, when used in its intended or reasonably foreseeable manner, created an unreasonable risk to the health of consumers, such as Plaintiff, and Defendants are therefore liable for the injuries sustained by Plaintiff.

82. As a direct and proximate result of the foregoing acts and omissions, Plaintiff was caused to suffer serious and dangerous side effects that contributed to her lung cancer and chronic lung disease, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain, and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications.

83. As a direct and proximate result of the foregoing acts and omissions the Plaintiff requires and/or will require more health care and services and did incur medical, health,

incidental, and related expenses. Plaintiff is informed and believes and further alleges that Plaintiff will in the future be required to obtain further medical and/or hospital care, attention, and services.

COUNT II
PRODUCTS LIABILITY: MANUFACTURING DEFECT

84. Plaintiff hereby incorporates by reference each of the allegations set forth in this Complaint as if fully set forth herein.

85. At all times herein mentioned, Defendants were involved in researching, designing, developing, manufacturing, testing, selling and/or distributing the Recalled Products, including the subject device, which are defective and unreasonably dangerous.

86. The subject device was expected to and did reach Plaintiff without a substantial change in its condition.

87. The finished subject device deviated, in terms of construction and quality, from the specifications or planned output in a manner that made it unreasonably dangerous.

88. The subject device prescribed to and used by Plaintiff was defective in its manufacture when it left the hands of Defendants in that it deviated from product specifications, posing a serious risk that the device would result in serious complications.

89. At all relevant times, the subject device was defectively manufactured by Defendants in that its design and formulation is more dangerous than what an ordinary consumer would expect when used in an intended and reasonably foreseeable manner.

90. At all relevant times, Defendants actively deceived users that their use of the Recalled Products posed safety risks that far outweighed any benefits.

91. Furthermore, the Recalled Products, including the subject device, were defectively

manufactured in that the PE-PUR foam comprising part of the devices can degrade into particles that enter the devices' air pathway and can off-gas certain chemicals. Plaintiff and other similarly situated consumers were unknowingly subjected to receiving different doses of toxins, carcinogens, and other deleterious components and contaminants when using the Recalled Products.

92. Without limitation, the Defendants breached their duty to exercise reasonable care in manufacturing, assembling, inspecting, and packaging the Recalled Products by their:

a) Failure to follow Good Manufacturing Practices ("GMPs");

b) Failure to adequately inspect/test the Recalled Products during the manufacturing process;

c) Failure to adequately determine/test the integrity of PE-PUR foam and its qualities, especially after the devices have aged.

d) Failure to adequately determine/test the purity of airflow through the Recalled Products' airway, especially after the devices have aged.

93. A reasonable manufacturer under the same or similar circumstances would have implemented appropriate manufacturing procedures to better ensure the quality of their devices.

94. Plaintiff was injured as a direct and proximate result of Defendants' failure to use reasonable care in the manufacturing, assembling, inspecting, and packaging of the subject device as described herein.

COUNT III
PRODUCTS LIABILITY: INADEQUATE WARNINGS OR INSTRUCTION

95. Plaintiff hereby incorporates by reference each of the allegations set forth in this Complaint as if fully set forth herein.

96. At all relevant times, Defendants designed, manufactured, assembled, inspected, tested (or not), packaged, labeled, marketed, advertised, promoted, supplied, distributed, and/or

sold the Recalled Products, including the subject device that Plaintiff used.

97. Defendants as the manufacturers, promoters, distributers, suppliers, and sellers of the Recalled Products, including the subject device, owed a duty to use reasonable care in the design, development, manufacture, marketing, promotion, distribution, supply, and sale of the Recalled Products, including the subject device.

98. The Defendants knew or, by the exercise of reasonable care, should have known, use of the subject device was dangerous, harmful, and injurious when used by Plaintiff in a reasonably foreseeable manner.

99. The Defendants knew or, by the exercise of reasonable care, should have known, ordinary consumers such as Plaintiff would not have realized the potential risks and dangers of the subject device.

100. The Defendants knew or, by the exercise of reasonable care, should have known, that the Recalled Products posed risks including headaches, irritation of the skin, eye, and respiratory tract, inflammation respiratory issues, asthma, adverse effect to organs (including the kidneys and liver), hypersensitivity, nausea, vomiting, and toxic and cancer, among other harmful effects, as described herein, that were known and knowable in light of scientific and medical knowledge that was generally accepted in the scientific community at the time of design, manufacture, and distribution of the Recalled Products.

101. The Defendants owed a duty to all reasonably foreseeable users to disclose the risks associated with the use of the Recalled Products.

102. The Defendants breached their duty of care by failing to use reasonable care in providing adequate warnings to Plaintiff's physician, in the subject device's labeling and packaging, and through marketing, promoting, and advertising of the subject device.

103. The foreseeable risk of harm from the subject device at issue in this Complaint could have been reduced or avoided by providing adequate instructions or warnings.

104. Defendants failed to provide adequate instructions or warnings regarding the risks of harm from the subject device at issue in this Complaint which were known by Defendants or should have been known by Defendants.

105. Defendants' failure to provide adequate instructions or warnings regarding the defective condition of the subject device rendered it unreasonably dangerous and/or not reasonably safe.

106. Defendants breached their duty by failing to use reasonable care by declining to include an expiration or best if "used by" date, which left open the potential for the devices' chemical and other properties to change in an even more harmful manner.

107. Defendants knew or should have known that using the subject device created a significantly increased risk of health harms.

108. The negligence of the Defendants, their agents, servants, and/or employees, included but was not limited to the following acts and/or omissions:

a) Defendants designed and developed the Recalled Products without thoroughly or adequately testing the devices;

b) Defendants sold the Recalled Products without making proper and sufficient tests to determine the dangers to the users;

c) Defendants failed to adequately and correctly warn the Plaintiff, the public, and the medical community of the risks associated with the Recalled Products;

d) Defendants advertised and recommended the use of the Recalled Products for treatment of sleep apnea and other conditions without sufficient knowledge as to the significance of risks;

e) Defendants failed to exercise reasonable care in designing the Recalled Products in a manner which was dangerous to the users;

f) Defendants negligently manufactured the Recalled Products in a manner which was dangerous to the users;

g) Defendants failed to exercise reasonable care when they collectively decided to conceal information concerning risks.

109. Additionally, Defendants under-reported, underestimated, and downplayed the serious dangers of the Recalled Products' association with health harms.

110. Defendants negligently compared the safety risk and/or dangers of the subject device with other forms of treatment for sleep apnea and similar conditions.

111. Defendants specifically failed to exercise reasonable care when they failed to accompany the subject device with proper and/or accurate warnings regarding *all* adverse side effects associated with the use of the subject device.

112. Even though Defendants knew or should have known that the Recalled Products caused unreasonably dangerous side effects, they made conscious decisions to downplay these risks and continue to market, manufacture, distribute, and/or sell the devices to physicians and patients, including the Plaintiff.

113. Defendants knew or should have known that consumers, such as Plaintiff, would foreseeably suffer injury because of Defendants' failure to exercise ordinary care, as set forth above.

114. Defendants' negligence was a proximate cause of Plaintiff's injuries, among many other health harms, which Plaintiff suffered and/or will continue to suffer.

115. Defendants owed Plaintiff a duty to provide reasonable complete and accurate information to Plaintiff, Plaintiff's healthcare providers, and the general public regarding the products at issue in this Complaint.

116. Defendants breached this duty by failing to adequately warn Plaintiff, Plaintiff's

physician and healthcare providers, and the public regarding the products at issue in this Complaint.

117. At all times herein mentioned, Defendants advertised, promoted, marketed, sold, and distributed the subject device that was used by the Plaintiff.

118. Defendants each had an independent duty and continuing duty to warn the medical community and Plaintiff's physicians about the significance of the risks and health harms of the subject device,

119. The subject device was defective due to inadequate warnings because Defendants knew or should have known that the product created a significantly increased risk of health injuries, including those suffered by Plaintiff, and failed to warn the medical community and Plaintiff's physician of the nature of such risks.

120. Defendants omitted and downplayed the significantly increased risks of harm and other health risks with the subject device that Defendants knew or should have known from previous testing and research even prior to subject device's FDA approval.

121. The subject device's labeling and warnings were defective because they omitted and inadequately warned of the device's health risks.

122. Although physicians are supposed to weigh the risks and benefits before prescribing a medical device, Defendants knew that their deliberate omissions would cause physicians, including Plaintiff's physician, to prescribe the subject device without being able to adequately weigh the risk of device's health risks.

123. If Defendants would have properly warned about the subject device's risks and/or other health harms, no reasonable physician, including Plaintiff's physician, would have recommended, or prescribed the subject device because the potential benefits of weight loss are

significantly outweighed by the risk of cancer and/or other harms.

124. Had Defendants reasonably provided adequate warnings, such warnings would have been heeded and no healthcare professional, including Plaintiff's physician, would have prescribed the subject device and no consumer, including Plaintiff, would have purchased and/or used the subject device.

125. As a direct and proximate result of the Defendants' failure to provide adequate warnings or instructions, Plaintiff has suffered harm, damages, economic loss, pain and suffering, and extensive medical treatment and medical expenses.

COUNT IV
PRODUCTS LIABILITY: BREACH OF IMPLIED WARRANTY

126. Plaintiff hereby incorporates by reference each of the allegations set forth in this Complaint as if fully set forth herein.

127. At all relevant times, Defendants, through their advertising and promotional materials, expressly and impliedly warranted and affirmed that the Recalled Products' purpose was to offer a reasonably safe treatment for sleep apnea and similar health problems.

128. Defendants touted the Recalled Products as safe, despite knowingly having never adequately researched or tested the devices to assess their safety before placing the devices on the market and promoting them to consumers.

129. Defendants intended to make Plaintiff and the public believe the Recalled Products were safe.

130. Defendants impliedly warranted that the products at issue in this Complaint and its component parts were merchantable and fit for the ordinary and intended purposes for which hip systems are used.

131. Defendants breached their implied warranty of merchantability since the Recalled Products were defective when created and designed, and do not conform with the promises represented on their labels.

132. Defendants failed to comply with merchantability requirements, as the Recalled Products do not achieve the ordinary purposes they advertise: a healthy treatment for respiratory conditions such as sleep apnea.

133. At all relevant times, Defendants had knowledge of the hazards and health risks posed by the Recalled Products when used.

134. At all relevant times, Defendants willfully failed to disclose the defects and health risks of the Recalled Products to Plaintiff and the consuming public.

135. Plaintiff relied to her detriment on the information publicized by Defendants.

136. Plaintiff was a foreseeable user of the products at issue in this Complaint.

137. At all times relevant to this Complaint, Plaintiff was in privity with Defendants.

138. Plaintiff used the products at issue in this Complaint for its ordinary and intended purpose.

139. The products at issue in this Complaint failed while being used for its ordinary and intended purpose.

140. Defendants sold and Plaintiff was prescribed and purchased the products at issue in this Complaint.

141. As a direct and proximate result of the Defendants' breach of implied warranty, Plaintiff has suffered harm, damages, economic loss, pain and suffering, and extensive medical treatment and medical expenses.

COUNT V
PRODUCTS LIABILITY: BREACH OF EXPRESS WARRANTY

142. Plaintiff hereby incorporates by reference each of the allegations set forth in this Complaint as if fully set forth herein.

143. Defendants expressly warranted by affirmation, promise, description, and sample to Plaintiff and Plaintiff's healthcare providers that the products at issue in this Complaint were of a quality and character suitable for implantation and extended safe use in Plaintiff.

144. Such representations by Defendants were meant to and did induce Plaintiff to purchase the products at issue in this Complaint.

145. The products at issue in this Complaint did not conform to the representations made by Defendants.

146. Defendants breached the express warranty it provided with the products at issue in this Complaint.

147. As a result of Defendants' conduct, Plaintiff suffered injuries and damages as alleged herein.

148. As a direct and proximate result of the Defendants' breach of warranty, as set forth above, Plaintiff has suffered harm, damages, economic loss, pain and suffering, and extensive medical treatment and medical expenses.

COUNT VI
NEGLIGENCE

149. Plaintiff hereby incorporates by reference each of the allegations set forth in this Complaint as if fully set forth herein.

150. At all relevant times, Defendants designed manufactured, assembled, inspected, tested, packaged, labeled, marketed, advertised, promoted, supplied, distributed, sold and/or

otherwise placed the Recalled Products into the stream of commerce, and therefore owed a duty of reasonable care to avoid causing harm to consumers, such as Plaintiff.

151. Defendants breached their duty in designing and manufacturing products that utilized PE-PUR foam, which can degrade into particles that enter the devices' air pathway and can give off-gas certain chemicals.

152. Through exercising reasonable care, Defendants either knew or should have known of the harms associated with including the PE-PUR foam in its Recalled Products.

153. As a result of Defendants' failure to exercise reasonable care in the design of the Recalled Products. Plaintiff and other similarly situated consumers were unknowingly subjected to receiving different doses of toxins, carcinogens, and other deleterious components and contaminants when using the Recalled Products.

154. Defendants additionally breached their duty in failing to inform their consumers, including Plaintiff, of the harm associated with their Recalled Products.

155. As a result of Defendants' failure to exercise reasonable care in instructing, or failing to instruct, its consumers of the risks and harms associated with the use of its Recalled Products, Plaintiff and other consumers suffered serious medical harm.

COUNT VII
FRAUD

156. Plaintiff hereby incorporates by reference each of the allegations set forth in this Complaint as if fully set forth herein.

157. At all relevant times, Defendants designed manufactured, assembled, inspected, tested, packaged, labeled, marketed, advertised, promoted, supplied, distributed, sold and/or otherwise placed the Recalled Products into the stream of commerce, and therefore owed a duty of reasonable care to avoid causing harm to consumers, such as Plaintiff.

158. Defendants knowingly made fraudulent statements regarding the safety of the Recalled Products and the substantial health risks associated with using the devices, all the while intending to deceive Plaintiff and the general public.

159. At all reasonable times, Defendants fraudulently misrepresented the Recalled Products as safe, when in fact the devices posed unreasonable risks of substantial bodily injury.

160. Due to these and other features, the Recalled Products are not fit for their ordinary, intended use as treatment devices for sleep apnea and similar respiratory conditions.

161. Defendants touted the Recalled Products as safe, despite a failure to adequately research or test the devices to assess their safety prior to marketing and promoting their use.

162. Defendants further falsely represented the nature and risks associated with the Recalled Products, and their marketing and strategy regarding the same, in general statements to the media, general public, and federal agencies.

163. Defendants' fraudulent misrepresentations and omissions were material facts that were essential to Plaintiff's decision to purchase the subject device.

164. Plaintiff was unaware that Defendants were knowingly concealing these material facts, which Plaintiff relied on to her detriment.

165. By knowingly misrepresenting this material information, Defendants breached their duty to protect Plaintiff and consumers.

166. Plaintiff justifiably relied to her detriment on Defendants' fraudulent statements. Had Plaintiff been adequately informed of the material facts concealed from her regarding the safety of the subject device, and not intentionally deceived by Defendants, he would not have acquired/purchased or used the subject device.

167. As a direct and proximate result of Defendants' fraudulent misrepresentations,

Plaintiff suffered and continues to suffer from the injuries and damages for which he is entitled to recovery, including but not limited to compensatory damages, consequential damages, interest, costs, and attorney fees.

COUNT VIII
FRAUDULENT CONCEALMENT

168. Plaintiff hereby incorporates by reference each of the allegations set forth in this Complaint as if fully set forth herein.

169. At all relevant times, Defendants designed, manufactured, assembled, inspected, tested, packaged, labeled, marketed, advertised, promoted, supplied, distributed, sold and/or otherwise placed the Recalled Products into the stream of commerce, and therefore owed a duty of reasonable care to avoid causing harm to those that used the devices, such as Plaintiff.

170. Defendants had a duty to disclose material facts about the Recalled Products that would substantially affect Plaintiff's and the general public's use when purchasing the devices.

171. At all reasonable times, Defendants fraudulently misrepresented the Recalled Products as safe, when in fact the devices posed unreasonable risks of substantial bodily injury. Therefore, the devices are not fit for their ordinary and intended uses.

172. Defendants actually knew about all of the above-pleaded facts.

173. At all relevant times, Defendants fraudulently and deceptively concealed their failure to adequately research or test the Recalled Products to assess their safety before marketing to susceptible users.

174. Defendants further falsely represented the nature and risks associated with the Recalled Products, and their marketing and strategy regarding the same, in general statements to the media, general public, and federal agencies.

175. Defendants' misrepresentations and omissions were material facts that were essential to Plaintiff's decision making when purchasing and using the subject device.

176. Plaintiff was completely unaware that Defendants were concealing these material facts.

177. Defendants intentionally deceived and concealed material information concerning the safety of the Recalled Products from Plaintiff and the general public, which had a direct impact on Plaintiff's and consumers' health and wellbeing.

178. Plaintiff relied to her detriment on Defendants' fraudulent concealment and omissions. Had Plaintiff been adequately informed of the material facts regarding the safety of the Recalled Products, and not intentionally deceived by Defendants, he would not have acquired/purchased, used, or been injured by the subject device.

179. As a direct and proximate result of Defendants' fraudulent concealment, Plaintiff suffered and continues to suffer from the injuries and damages for which he is entitled to recovery, including but not limited to compensatory damages, consequential damages, interest, costs, and attorney fees.

PUNITIVE DAMAGES

180. Plaintiff hereby incorporates by reference each of the allegations set forth in this Complaint as if fully set forth herein.

181. Defendants' conduct described herein consisted of oppression, fraud, and/or malice, and was done with advance knowledge, conscious disregard of the safety of others, and/or ratification by Defendants' officers, directors, and/or managing agents.

182. Despite their knowledge of the Recalled Products' propensity to cause serious injuries, Defendants chose profits over the safety of American citizens suffering with sleep

apnea when they sought to create and market a device posing significant health risks.

183. Despite having substantial information about the Recalled Products' serious and unreasonable side effects, Defendants intentionally and recklessly failed to adequately warn the public, physicians, and the medical community.

184. Further, despite having substantial information about the Recalled Products' serious and unreasonable side effects, Defendants failed to make the decision to pull the devices from the market after receiving indications and after receiving reports from consumers who were experiencing serious injuries associated with the use of the devices.

185. Defendants downplayed and recklessly disregarded their knowledge of the defective nature of the Recalled Products' potential for causing serious injuries.

186. Defendants chose to do nothing to warn the public about serious and undisclosed side effects with the Recalled Products.

187. Defendants recklessly failed to warn and adequately instruct physicians, including Plaintiff's physician, regarding the increase in reports from consumers who were experiencing serious injuries associated with the use of the Recalled Products.

188. Consequently, Defendants are liable for punitive damages in an amount to be determined by the jury.

V. CONCLUSION

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for relief and judgment against the Defendants jointly and severally as follows:

(a) That the Court enter a judgment against the Defendants for all general and compensatory damages allowable to Plaintiff in a sum in excess of the jurisdictional minimum of this Court, including all damages specified above;

(b) For all medical, incidental, and hospital expenses according to proof;

(c) For pre-judgment and post-judgment interest as provided by law;

(d) For a full refund of all purchase costs Plaintiff paid for the subject device;

(e) That the Court enter a judgment against Defendants for all special and consequential damages allowable to Plaintiff in excess of the jurisdictional minimum of this Court, including all damages specified above;

(f) For punitive damages in an amount in excess of any jurisdictional minimum of this Court and in an amount sufficient to impress upon Defendants the seriousness of their conduct and to deter similar conduct in the future;

(g) That the Court enter a judgment against the Defendants for all other relief sought by Plaintiff under the present Complaint for Damages;

(h) For attorneys' fees, expenses, and costs of this action; and

(i) That the Court grant Plaintiff such further relief which the Court deems appropriate.

(j)

DEMAND FOR JURY TRIAL

Plaintiff demands a trial by jury on all counts and as to all issues.

Dated: December 22, 2021

Respectfully Submitted,

By:

/s/ Paula S. Bliss

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